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Human Papillomavirus Self-sampling for Cervical Cancer Screening among Women in sub-Saharan Africa: A Scoping Review Protocol

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Abstract

Introduction

Evidence shows that women in sub-Saharan Africa (SSA) have high rates of cervical cancer (CC) mortality compared to women in high-income countries (HICs). Effective screening programmes have significantly reduced the burden of CC in HICs. Human papillomavirus (HPV) self-sampling (HPVSS) has been reported to be an acceptable screening method among women in underserved communities. Here we outline a protocol for a scoping review aimed at mapping literature on the use and acceptability of HPVSS for screening CC in SSA to reveal gaps to guide future research and practice.

Methods and Analysis

The scoping review protocol was developed according to Arksey and O'Malley and Levac *et al*, and guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR). We will search Scopus, PubMed, EBSCOHost, and Web of Science databases for studies presenting evidence on HPVSS in SSA. We will search grey literature in the form of dissertations/theses, conference proceedings, websites of international organizations such as the World Health Organisation, and relevant government reports reporting evidence on HPVSS programs for screening CC among women in SSA. We will employ NVIVO version 12 software package to extract the relevant themes from the included articles. We will use the mixed method appraisal tool (MMAT) version 2018 to appraise the quality of the included studies.

Ethics and dissemination

No ethical approval is needed for the study as it will not include animals or human participants. The results of the proposed scoping review will be disseminated electronically, in print, and through conference presentations as well as key stakeholder meetings.

Keywords: Women; Human papillomavirus DNA tests; Self-sampling; sub-Saharan Africa

Article Summary

Strengths and Limitations of this study:

- The results of this review will establish a baseline understanding of the use of Human papillomavirus self-sampling for cervical cancer screening in sub-Saharan Africa and expose gaps that exist in cervical cancer screening in sub-Saharan Africa
- Here we propose the use of an established scoping review methodology with a comprehensive search strategy that includes grey literature.
- The study will conduct a formal quality assessment of included studies guided by an established mixed methods appraisal tool.
- A limitation of the review is the potential to miss relevant articles given that the findings will be limited to articles written in English.

Introduction

Despite being a largely preventable disease, cervical cancer (CC) incidence and mortality remain important indicators of global health inequality.[1] An estimated 90% of the globally recorded CC-related deaths are in low-and middle-income countries (LMICs), of which 8 out of 10 are recorded within the sub-Saharan African (SSA) region.[2] SSA bears the highest burden of the human immunodeficiency virus (HIV) infection globally and the high

prevalence of HPV infection in this population further increases the burden of CC in SSA.[3 4] CC screening has significantly reduced the burden of CC in high-income countries (HICs).[3 5] However, in low-income countries, the burden of CC incidence and mortality is very high due to the lack of organised CC screening services and low uptake of available screening services by women.[6-8] Human papillomavirus (HPV) DNA testing on self-collected specimens has been shown to increase the participation of women in CC screening programmes by reducing individual and health system-related barriers to screening particularly in low-resource settings.[9 10] HPV self-sampling (HPVSS) is a process where a woman who wants to know whether she has a high-risk HPV infection uses a kit to collect a cervicovaginal sample from herself.[9-11]

Elimination of CC is an important component of sustainable development goals (SDGs) to tackle global health inequalities and non-communicable diseases.[12] In 2018 the World Health Organisation (WHO) made a global call for the eli mination of CC by end of the century.[13] Under the call, The WHO targets to screen 70% of women with a high-performance test by 35, and again by 45 years of age by 2030.[13] The WHO has recommended the use of a high-performance test like HPV DNA test for the screening of CC in women.[14]

The burden of CC in SSA is profound and complex. HPVSS may be an effective means of ensuring screening services for underserved women who fail to access screening services due to a variety of reasons. Although HPVSS is established as an effective strategy for detecting CC by identifying women at risk, it is less clear whether this is an acceptable screening option for women in SSA. The purpose of this scoping review is to map the current literature on the use and acceptability of HPVSS as a primary screening method in SSA. It is anticipated that findings from this study will enable the researchers to identify gaps in the subject matter and guide future research towards improved and increased participation of women in CC screening programmes. The results of this study will also guide policymakers

in crafting programmes that increase access to CC screening services to underserved women in SSA.

Methods and Analysis

This proposed scoping review is part of a multi-phase Ph.D. study investigating the use and acceptability of HPVSS for CC screening among women in SSA. The review will be developed according to the methodological framework proposed by Arksey and O'Malley[15] and Levac et al,[16] and guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR).[17] According to Arksey and O'Malley framework,[15 16] a scoping review follows five stages: (i) identify the research question, (ii) identify relevant studies, (iii) select eligible studies, (iv) charting the data, and (v) collating, summarising and reporting the results. Arksey and O'Malley also proposed an optional sixth stage, the consultation with key stakeholders to provide insights beyond those found in the literature. This scoping review will not include consultation with stakeholders.

Eligibility of the research question for a scoping review

The research question is: What is the evidence on the use and acceptability of HPVSS for CC screening of women in SSA?

To determine the eligibility of the proposed research question for a scoping review, we used the Population, Concept, and Context (PCC) nomenclature as depicted in Table **1**.

Table **1:** PCC for determining the eligibility of the research question.

Population	Asymptomatic females; 25 years and older residing in sub-Saharan Africa
Concept	HPV self-sampling programmes conducted between January 2011 and June 2021
Context	sub-Saharan Africa

Identification of relevant studies

We will conduct a comprehensive search of relevant literature from the following electronic databases for articles published between January 2011 and June 2021: Scopus, PubMed, EBSCOhost, and Web of Science. In addition, we will search on ResearchGate as well as grey literature from university dissertations and theses from institutional repositories, government, and international organizations' reports such as the WHO. We will identify additional relevant studies by manually searching all references cited in the included studies to identify studies that have not been indexed by the electronic databases.

The comprehensive search strategy will be co-developed by the principal investigator (PI), subject specialist, and university librarian to ensure the correct use of indexing terminology and Medical Subject Headings (MeSH) terms. The following keywords or MeSH terms will be used: 1) "cervical cancer" 2) "human papillomavirus" 3) "self-sampling" 4) "sub-Saharan Africa". Keywords may be refined to suit each database. Each search will be documented in detail showing the keywords/MeSH terms, date of search, electronic database, and the number of retrieved studies. We piloted the search strategy on one of the electronic databases and the results of the search are presented in Table **2**.

Table **2:** Results of pilot search in PubMed.

Date of search	Electronic Database	Keywords/MeSH terms	Number of retrieved studies
05/07/2021	Pubmed	((("Uterine Cervical Neoplasms"[Mesh] OR "Uterine Cervical Neoplasm*"[tw] OR "Cervical Cancer"[tw] AND (female[Filter])) OR ("Alphapapillomavirus"[Mesh] OR Alphapapillomavirus[tw] OR "Human papillomavirus*"[tw] OR HPV[tw] OR papillomavirus*[tw] AND (female[Filter]))) AND ("Self Administration"[Mesh] OR self-sampl*[tw] OR "self collect*"[tw] OR "self Administ*"[tw] OR "self screen*"[tw] AND (female[Filter]))) AND ("Africa South of the Sahara"[Mesh] OR "Africa Sub-Saharan"[tw] OR "Subsaharan Africa"[tw] OR "Sub-Sahara africa"[tw] AND (female[Filter])) Filters: in the last 10 years, Female	117

Selection of eligible studies

Relevant studies will be selected using the following criteria:

Inclusion criteria

- Articles reporting on evidence of HPVSS in women 25 years and older

- Articles reporting on evidence of HPVSS in women residing in SSA
- Articles published between January 2011 and June 2021

Exclusion criteria

Articles will be excluded from the scoping review if they have the following characteristics:

- Articles that report on other methods of CC screening
- Articles reporting on evidence of HPVSS in women residing outside SSA
- Articles published before January 2011 and after June 2021
- Review articles
- Articles that are written in other languages other than English

All eligible articles will be exported to an Endnote 20 library and duplicates will be removed. The articles will be screened in two stages, namely abstract and full article screening. The PI will screen titles and abstracts in parallel with the co-reviewer. After screening titles and abstracts, the reviewers will discuss any discrepancies in selected articles until a consensus is reached. Two independent reviewers will then screen the full texts of articles selected during the first stage. A third screener will resolve any discrepancies in selected articles after the full-text screening. Both abstract and full article screening will be guided by the above inclusion/exclusion criteria.

The level of agreement between screeners' results after screening abstracts and full articles will be determined by calculating Cohen's kappa statistic. The kappa statistic will be interpreted as follows: values < 0.1 indicate no agreement and 0.10-0.20 indicate none to slight, 0.21-0.40 as fair, 0.41-0.60 as moderate, 0.61-0.80 as substantial, and 0.81-1.00 as almost perfect agreement. We will report the screening results following the Preferred

Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines[18] (Figure **1**).

Charting the data

We developed a data charting form to capture information from each relevant study. Two independent reviewers will pilot the data charting form before commencing with the scoping review. The data charting form will be modified based on the reviewers' feedback and it will constantly be updated throughout the scoping review. The form that will be used for data charting is presented in Table **3**.

Table **3:** Data charting form.

Author & year of publication
Publication journal
Title of study
Aim of study
Study population
Study setting
Geography (SSA country where the study was conducted)
Number of women (sample size)
Age of women
Study design
Method of delivery of self-sampling kits (home-based or hospital-based)
Main findings
Other significant findings

Collating, summarizing, and reporting the results

We will employ NVivo version 12 to conduct content thematic analysis of the included studies. We will present a narrative account of the findings presenting the main concepts from the included articles in line with our research question.

Quality appraisal

We will use the mixed method appraisal tool (MMAT) version 2018 to evaluate the quality of the included studies.[19] Two independent reviewers will carry out the quality appraisal process. The following percentage scores will be used to grade the quality of evidence: i) ≤50% will represent low quality evidence ii) 51-75% will represent average quality evidence iii) 76-100% will represent high-quality evidence. This quality appraisal method will enable us to appraise a variety of study methods, i.e. qualitative, quantitative or mixed methods studies.[19]

Ethical considerations

No ethical approval is needed for the study because it will not include animals or human participants.

Patient and public involvement

In this protocol, there was no involvement of patients and the public.

Discussion

The elimination of CC is in line with the 2030 agenda for SDG 3 and targets that seek to ensure healthy lives and promote well-being for all at all ages.[12] The majority of women in LMICs including SSA lack access to CC screening services and where the services are available they are underutilised due to several barriers.[5] HPVSS has been demonstrated to be an acceptable screening method for underserved women that increases their participation in

CC screening programmes.[20] There have been several HPVSS interventions that have been conducted in SSA, however, a few studies have synthesised evidence on the acceptability of the intervention.[21] The proposed scoping review will map evidence on the use and acceptability of HPVSS in SSA. Getting prior information on studies conducted in SSA will help guide the implementation of HPVSS for CC screening in the region. The scoping review is part of a larger study that seeks to pilot an HPVSS programme for CC screening in Zimbabwe. This intervention has the potential to increase access to underserved women as well as increase their participation in CC screening.

In this scoping review, we will include evidence on the use of HPVSS for screening women aged 25 years and older, the WHO recommends HPV testing for women aged 30 years and above because most HPV infections in young women are transient.[14] We have chosen to include studies published in the last decade (2011-2021) to capture recent evidence on HPVSS in SSA. In addition, the WHO recommended the use of HPV testing for CC screening in 2013,[14] therefore, we are likely to find studies where HPVSS interventions have been implemented in SSA in response to the WHO recommendation. Furthermore, studies reporting evidence on other methods of CC screening other than HPVSS will not be considered for this review as well as studies conducted outside SSA. We have chosen to map evidence on HPVSS in SSA because it has the highest burden of CC in the world and findings are more likely to apply to Zimbabwe which is a country in SSA.

We anticipate finding relevant studies reporting on the use of HPVSS for screening CC in SSA. The findings of this review may be of importance to policymakers involved in designing interventions to increase access to CC screening services to underserved women. Furthermore, the findings will guide further research on best practices of implementing an

HPVSS programme in low-resource settings. This review will be disseminated electronically or in print and presented at scientific conferences.

Abbreviations

CC: Cervical cancer

HPV: Human papillomavirus

HPVSS: Human papillomavirus self-sampling

LMICs: Low middle-income countries

MeSH*:* Medical Subject Headings

MMAT: Mixed method appraisal tool

PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for scoping review

SSA: sub-Saharan Africa

Declarations

Acknowledgements

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Funding

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Availability of data and materials

All data generated or analysed during this study will be included in the scoping review article.

Author Contributions

MD conceptualized the study and prepared the draft proposal under the supervision of TPM-T. MD, TD, and TPM-T contributed to the development of the background and planned the output of the research as well as the design of the study. KK contributed to the development of the search strategy. MD prepared the manuscript, and TD and TPM-T critically reviewed it. All authors (MD, TD, KK and TPM-T) contributed to the reviewed draft version of the manuscript and approved the final version.

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

None declared.

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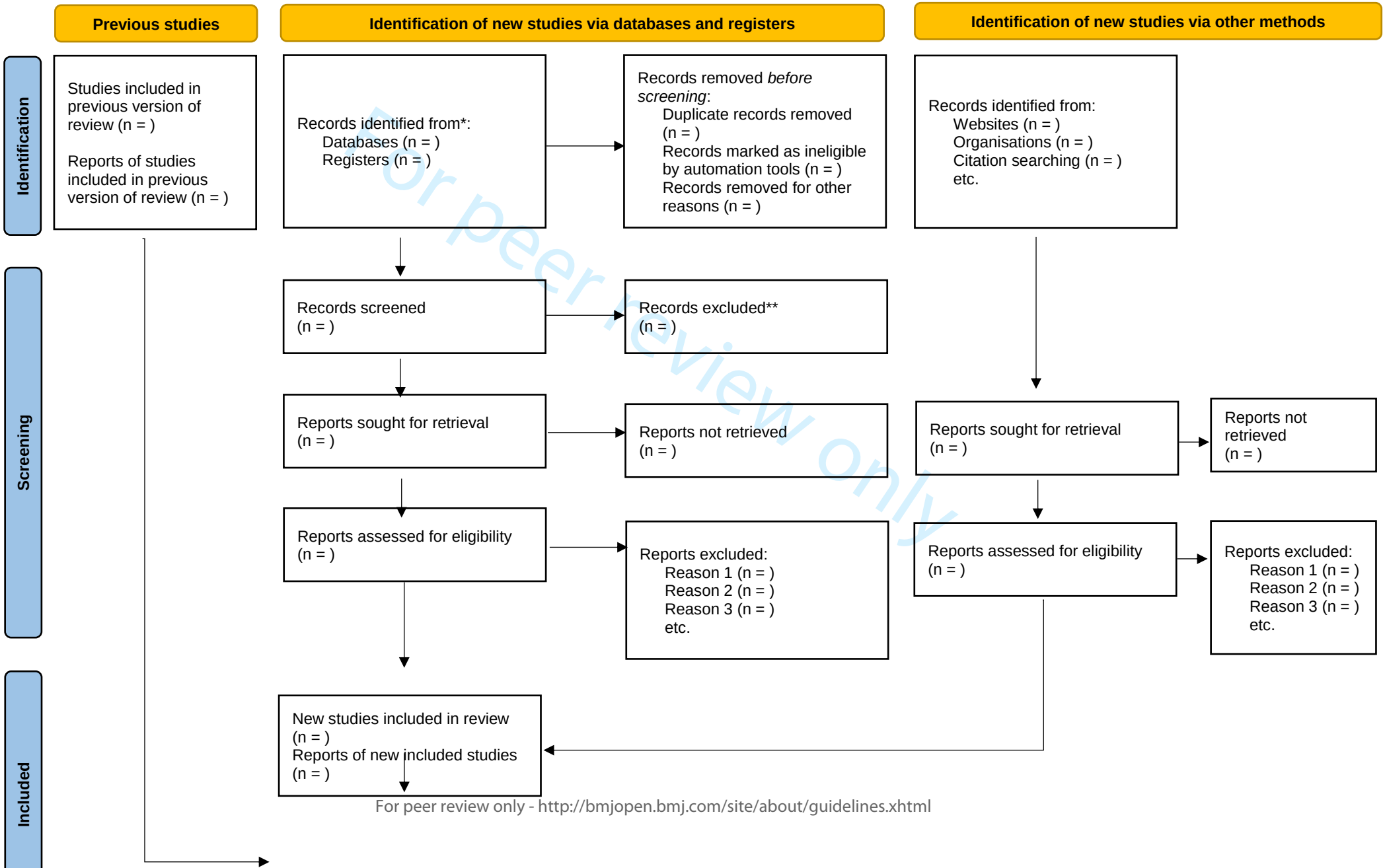
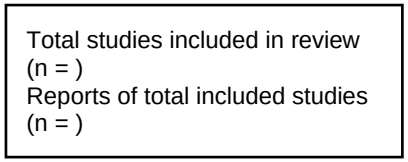
Figure 1: PRISMA flow diagram of the study selection process

Figure. 1





PRISMA flow diagram of the study selection process

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist

Section and topic	Item No	Checklist item	Page number
ADMINISTRATIVE INFORMATION			
Title:		**Human Papillomavirus Self-sampling for Cervical Cancer Screening among Women in sub-Saharan Africa: A Scoping Review Protocol**	
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	N/A
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	8
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	N/A
Support:			
Sources	5a	Indicate sources of financial or other support for the review	8
Sponsor	5b	Provide name for the review funder and/or sponsor	8
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	8
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	3
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	4
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	4-6
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	4-5
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	5

Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	5-6
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	5-6
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	6
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	4
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	6
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	N/A
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	N/A
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	N/A
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	N/A
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	6-7
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	N/A
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	N/A

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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Human Papillomavirus Self-sampling for Cervical Cancer Screening among Women in sub-Saharan Africa: A Scoping Review Protocol

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Abstract

Introduction

Evidence shows that women in sub-Saharan Africa have high rates of cervical cancer (CC) mortality compared to women in high-income countries. Effective screening programmes have significantly reduced the burden of CC in high-income countries. Self-sampling for Human papillomavirus testing (HPVSS) has been reported to increase the participation and engagement of women in CC screening. Before HPVSS can be introduced for CC screening there is a need to establish its acceptability among end-users to ensure the increase in CC screening rates. Here we outline a protocol for a scoping review aimed at mapping literature on the use and acceptability of HPVSS for screening CC in sub-Saharan Africa to reveal gaps to guide future research and practice.

Method

The scoping review protocol was developed according to Arksey and O'Malley and Levac *et al*, and guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews. We will search Scopus, PubMed, Medline Ovid, Cochrane, and Web of Science databases for evidence on the use and acceptability of HPVSS published between January 2011 and July 2021. We will also search grey literature in the form of dissertations/theses, conference proceedings, websites of international organizations such as the World Health Organisation, and relevant government reports reporting evidence on HPVSS programs for screening CC among women in sub-Saharan Africa.

Ethics and dissemination

No ethical approval is needed for the study as it will not include animals or human participants. The results of the proposed scoping review will be disseminated electronically in peer-reviewed journals, in print, and through conference presentations.

Keywords: Women; Human papillomavirus DNA tests; Self-sampling; cervical cancer, sub-Saharan Africa

Article Summary

Strengths and Limitations of this study:

- The results of this review will establish a baseline understanding of the use and acceptability of HPVSS for CC screening in SSA and expose gaps that exist
- Here we propose the use of an established scoping review methodology with a comprehensive search strategy that includes grey literature.
- The study will conduct a formal quality assessment of included studies guided by an established mixed methods appraisal tool.
- A limitation of the review is the potential to miss relevant articles given that review articles will not be considered for the study

Introduction

Despite being a largely preventable disease, cervical cancer (CC) incidence and mortality remain important indicators of global health inequality.[1] An estimated 90% of the globally recorded CC-related deaths are in low-and middle-income countries (LMICs), of which 8 out of 10 are recorded within the sub-Saharan African (SSA) region.[2] In addition, the high burden of HIV/AIDS further worsens the problem of CC in SSA.[3 4] CC screening has significantly reduced the burden of CC in high-income countries (HICs).[3 5] However, in low- and middle-income countries (LMICs), the burden of CC incidence and mortality is very high

due to the lack of organised CC screening services and low uptake of available screening services by women.[6-8] In 2018 the World Health Organisation (WHO) made a global call for the elimination of CC by end of the century.[9] Under the call, The WHO targets to screen 70% of women with a high-performance test by 35, and again by 45 years of age by 2030.[9] The WHO has recommended the use of a high-performance test like Human papillomavirus (HPV) DNA test for the screening of CC in women [10] and recent WHO guidelines now advocate for the use of self-samping to screen CC among women.[11]

Self-sampling for HPV testing (HPVSS) is a process where a woman who wants to know whether she has a high-risk HPV infection uses a kit to collect a cervicovaginal sample from herself.[12-14] HPVSS has been shown to increase the participation of women in CC screening programmes by reducing individual and health system-related barriers to screening particularly in low-resource settings.[12 14] The lack of privacy, fear and shame of a pelvic exam and long distances to health facilities have been cited as barriers to CC screening. [8 12] Important considerations for introducing HPVSS should consider the follow-up of women who screen positive for HPV as well as triage options with another method such as visual inspection with acetic acid to prevent overtreatment of HPV infections which in most cases are transient.[12 13] Before HPVSS can be incorporated into national screening programmes there is a need to determine its acceptability among the targeted end-users.

The purpose of this scoping review is to map the literature evidence on the use and acceptability of HPVSS as a primary screening method in SSA. It is anticipated that findings from this study will enable the researchers to identify research gaps and guide future research towards improved and increased participation of women in CC screening programmes. The results of this study will also guide policymakers in designing CC screening programmes based on HPVSS that are more acceptable to end-users to increase the uptake of CC screening services in SSA.

Methods and Analysis

This proposed scoping review is part of a multi-phase Ph.D. study investigating the use and acceptability of HPVSS for CC screening among women in SSA. The review will be developed according to the methodological framework proposed by Arksey and O'Malley[15] and Levac et al,[16] and guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR).[17] According to Arksey and O'Malley framework,[15 16] a scoping review follows five stages: (i) identify the research question, (ii) identify relevant studies, (iii) select eligible studies, (iv) charting the data, and (v) collating, summarising and reporting the results. Arksey and O'Malley also proposed an optional sixth stage, the consultation with key stakeholders to provide insights beyond those found in the literature. This scoping review will not include consultation with stakeholders.

Eligibility of the research question for a scoping review

The research question is: What is the evidence on the use and acceptability of HPVSS for CC screening of women in SSA?

The main objective is: To map out evidence on the use and acceptability of HPVSS for CC screening of women in SSA.

We used the following key elements To determine the eligibility of the proposed research question for a scoping review, We used the following elements: (Population, Concept, and Context) to conceptualize the review question as depicted in Table 1.

Table 1: PCC for determining the eligibility of the research question.

Population	Asymptomatic females; 25 years and older residing in SSA
Concept	HPVSS programmes conducted between January 2011 and June 2021
Context	Countries in the SSA region

Identification of relevant studies

We will conduct a comprehensive search of relevant literature from the following electronic databases for articles published between January 2011 and June 2021: Scopus, PubMed, Medline Ovid, Cochrane, and Web of Science databases. We will search for randomized controlled trials, non-randomized controlled trials, and observational studies that reported evidence on HPVSS for CC screening. Review articles (narrative, scoping, systematic, meta-analysis, and meta-synthesis) were excluded. In addition, we will search for grey literature from university dissertations and theses from institutional repositories, government, and international organizations' reports such as the WHO. We will identify additional relevant studies by manually searching all references cited in the included studies to identify studies that have not been indexed by the electronic databases. The authors of the included articles will be contacted for missing data and review articles will not be included in this study.

The comprehensive search strategy will be co-developed by the principal investigator (PI), subject specialist, and university librarian to ensure the correct use of indexing terminology and Medical Subject Headings (MeSH) terms. The following keywords or MeSH terms will be used: 1) "cervical cancer" 2) "human papillomavirus" 3) "self-sampling" 4) "sub-Saharan Africa". Keywords may be refined to suit each database. Each search will be documented in detail showing the keywords/MeSH terms, date of search, electronic database, and the number of retrieved studies. We piloted the search strategy on all the electronic databases and the results of the search are presented in Supplementary File 1.

Selection of eligible studies

Relevant studies will be selected using the following criteria:

Inclusion criteria

- Articles reporting on evidence of HPVSS in women 25 years and older

- Articles reporting on the acceptability of HPVSS for CC screening
- Articles reporting on evidence of HPVSS in women residing in SSA
- Articles published between January 2011 and June 2021

Exclusion criteria

Articles will be excluded from the scoping review if they have the following characteristics:

- Articles that report on other methods of CC screening articles that do not report on acceptability, willingness, or preferences for HPVSS
- Articles reporting on evidence of HPVSS in women residing outside SSA
- Articles published before January 2011 and after June 2021
- Review articles

All eligible articles will be exported to an Endnote 20 library and duplicates will be removed. The articles will be screened in three stages, namely title, abstract and full article screening. The PI will screen titles and abstracts in parallel with the co-reviewer. After screening titles and abstracts, the reviewers will discuss any discrepancies in selected articles until a consensus is reached. Two independent reviewers will then screen the full texts of articles selected during the first stage. A third screener will resolve any discrepancies in selected articles after the full-text screening. Both abstract and full article screening will be guided by the above inclusion/exclusion criteria.

The level of agreement between screeners' results after screening abstracts and full articles will be determined by calculating Cohen's kappa statistic. The kappa statistic will be interpreted as follows: values < 0.1 indicate no agreement and 0.10-0.20 indicate none to slight, 0.21-0.40 as fair, 0.41-0.60 as moderate, 0.61-0.80 as substantial, and 0.81-1.00 as almost perfect agreement. We will report the screening results following the Preferred

Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines[18] (Figure **1**).

Charting the data

We developed a data charting form to capture information from each relevant study. Two independent reviewers will pilot the data charting form before commencing with the scoping review. The data charting form will be modified based on the reviewers' feedback and it will constantly be updated throughout the scoping review. The form that will be used for data charting is presented in Table **2**.

Table 2. Data charting form.

Author & year of publication
Aim of study
Study population
Study setting (rural or urban)
Geography (SSA country where the study was conducted)
Number of women (sample size)
Age of women
Study design
Setting of self-sampling kits (health facility or home/community based)
Type of self-sampling device used
Main findings (acceptability of HPVSS)
Other significant findings

Collating, summarizing, and reporting the results

We will employ NVivo version 12 to extract themes from the included studies.We will conduct a content thematic analysis of the included studies. We will present a narrative account of the findings presenting the main concepts from the included articles in line with our research question. Our study context is acceptability of self-sampling for HPV testing which is defined as the ease and comfort or willingness to perform cervicovaginal self-sampling[19]

Quality appraisal

We will use the mixed method appraisal tool (MMAT) version 2018 to evaluate the quality of the included studies.[20] Two independent reviewers will carry out the quality appraisal process. The following percentage scores will be used to grade the quality of evidence: i) ≤50% will represent low quality evidence ii) 51-75% will represent average quality evidence iii) 76-100% will represent high-quality evidence. This quality appraisal method will enable us to appraise a variety of study methods, i.e. qualitative, quantitative or mixed methods studies.[20]

Ethics and dissemination

No ethical approval is needed for the study because it will not include animals or human participants. The findings of this review will be disseminated electronically in peer-reviewed journals or print and presented at scientific conferences.

Patient and public involvement

In this protocol, there was no involvement of patients and the public.

Discussion

The elimination of CC is in line with the 2030 agenda for SDG 3 and targets that seek to ensure healthy lives and promote well-being for all at all ages.[21] The majority of women in

LMICs including SSA lack access to CC screening services and where the services are available they are underutilised due to several barriers.[5] HPVSS has been demonstrated to be an acceptable screening method for underserved women that increases their participation and engagement in CC screening programmes.[22] There have been several HPVSS interventions that have been conducted in SSA, however, a few studies have synthesised evidence on the acceptability of the intervention.[23] The proposed scoping review will map evidence on the use and acceptability of HPVSS in SSA. Getting prior information on studies conducted in SSA will help guide the implementation of HPVSS for CC screening in the region and other LMICs. The scoping review is part of a larger study that seeks to pilot an HPVSS programme for CC screening in Zimbabwe. The scoping review will synthesise existing literature evidence and reveal gaps in research and guide the methodology of the main study. This intervention has the potential to increase access to underserved women as well as increase their participation in CC screening.

In this scoping review, we will include evidence on the use and acceptability of HPVSS for screening women aged 25 years and older, the WHO recommends HPV testing for women aged 30 years and above because most HPV infections in young women are transient.[10] We have chosen to include studies published in the last decade (2011-2021) to capture recent evidence on HPVSS in SSA. In addition, the WHO recommended the use of HPV testing for CC screening in 2013,[10] therefore, we are likely to find studies where HPVSS interventions have been implemented in SSA in response to the WHO recommendation. Furthermore, studies reporting evidence on other methods of CC screening other than HPVSS will not be considered for this review as well as studies conducted outside SSA. A limitation of the review is the potential to miss relevant articles given that review articles will not be

considered for the study and also the potential to miss important studies from other LMICs outside SSA.

We have chosen to map evidence on HPVSS in SSA because it has the highest burden of CC in the world and findings are more likely to apply to Zimbabwe which is a country in SSA. We anticipate finding relevant studies reporting on the use and acceptability of HPVSS for screening CC in SSA. The findings of this review will help policymakers to design interventions that increase the uptake of CC screening services in SSA. Furthermore, the findings will guide further research on best practices of implementing an acceptable HPVSS programme in LMICs.

Abbreviations

CC: Cervical cancer

HPV: Human papillomavirus

HPVSS: Human papillomavirus self-sampling

LMICs: Low middle-income countries

MeSH*:* Medical Subject Headings

MMAT: Mixed method appraisal tool

PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for scoping review

SSA: sub-Saharan Africa

Declarations

Acknowledgements

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Author Contributions

MD conceptualized the study and prepared the draft proposal under the supervision of TPM-T. MD, TD, and TPM-T contributed to the development of the background and planned the output of the research as well as the design of the study. KK contributed to the development of the search strategy. MD prepared the manuscript, and TD and TPM-T critically reviewed it. All authors (MD, TD, KK, and TPM-T) contributed to the reviewed draft version of the manuscript and approved the final version.

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

None declared.

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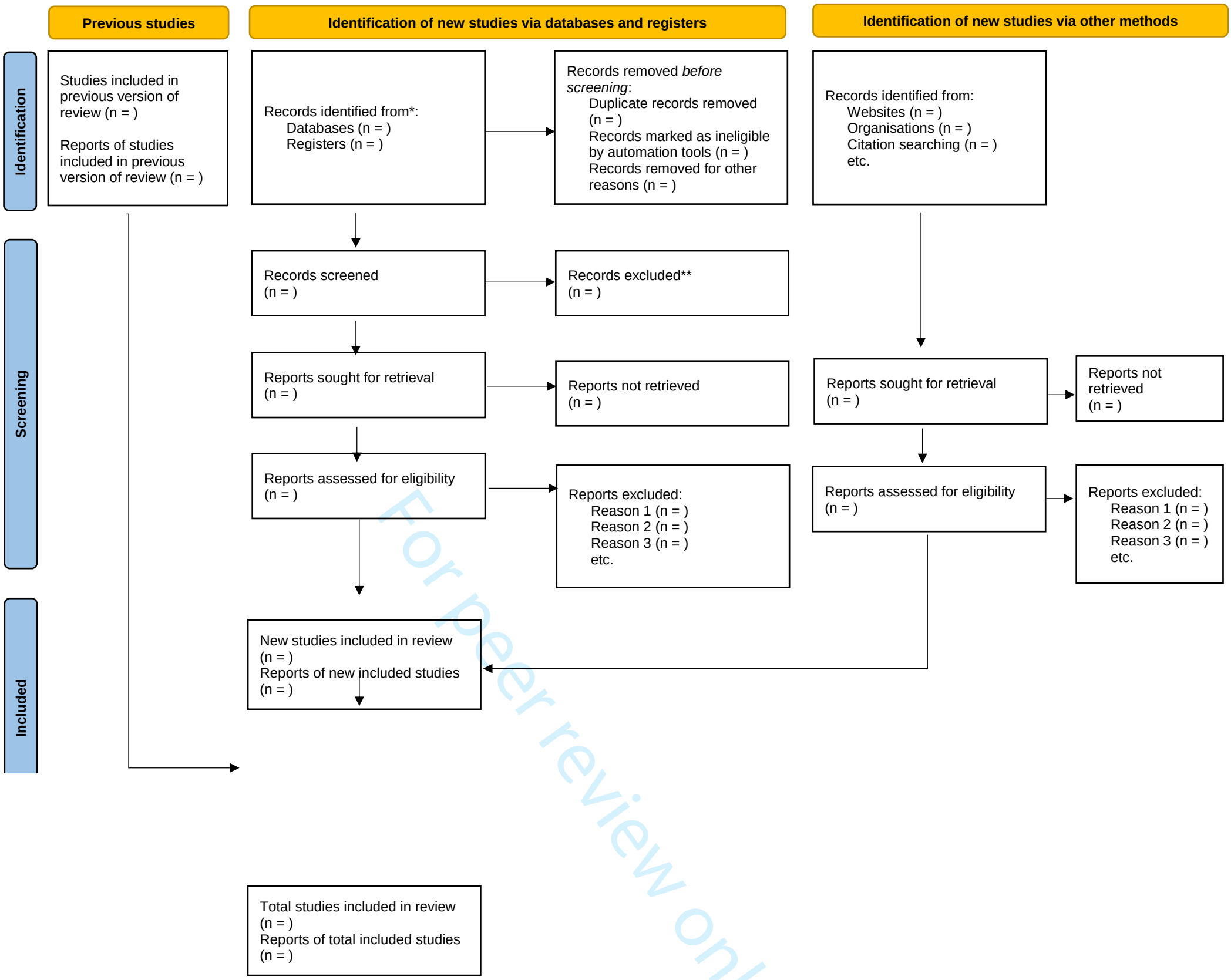
Figure 1: PRISMA flow diagram of the study selection process

Figure. 1



PRISMA flow diagram of the study selection process

Supplementary File 1: Results of the search strategy for electronic databases and grey literature

Date of search	Electronic Database	Keywords/MeSH terms
14-06-2021	Web of Science	Human papillomavirus*" OR alphapapillomavirus OR hpv OR papillomavirus* OR "Cervical cancer*" OR "Uterine Cervical Neoplasm*" OR "cancer of the cervix" OR "uterine cervix tumor" AND "self-sampling" OR "self sampl*" OR "self collect*" OR "self screen*" OR screening AND Africa OR "sub-Saharan Africa" OR "Africa South of the Sahara" AND female OR woman OR women NOT algeria OR egypt OR libya OR morocco OR tunisia
06-07-2021	PubMed	((("Uterine Cervical Neoplasms"[Mesh] OR "Uterine Cervical Neoplasm*"[tw] OR "Cervical Cancer"[tw] AND (female[Filter])) OR ("Alphapapillomavirus"[Mesh] OR Alphapapillomavirus[tw] OR "Human papillomavirus*"[tw] OR HPV[tw] OR papillomavirus*[tw] AND (female[Filter]))) AND ("Self Administration"[Mesh] OR self-sampl*[tw] OR "self collect*"[tw] OR "self Administ*"[tw] OR "self screen*"[tw] AND (female[Filter]))) AND ("Africa South of the Sahara"[Mesh] OR "Africa Sub-Saharan"[tw] OR "Subsaharan Africa"[tw] OR "Sub-Sahara africa"[tw] AND (female[Filter])) Filters: in the last 10 years, Female
06-07-2021	Scopus	(TITLE-ABS-KEY(Africa* OR "sub-Saharan Africa" OR SS OR "Africa South of the Sahara" OR "Subsahara* Africa") AND TITLE-ABS-KEY("Human papillomavirus*" OR alphapapillomavirus OR hpv OR papillomavirus* OR "Cervical cancer*" OR "Uterine Cervical Neoplasm*" OR "cancer of the cervix" OR "uterine cervix tumor") AND TITLE-ABS-KEY("self-sampling" OR "self sampl*" OR "self collect*" OR "self screen*" OR screening) AND NOT TITLE-ABS-KEY(Algeria OR Egypt OR Libya OR Morocco OR Tunisia)) AND (LIMIT-TO (PUBYEAR,2021) OR LIMIT-TO (PUBYEAR,2020) OR LIMIT-TO (PUBYEAR,2019) OR LIMIT-TO (PUBYEAR,2018) OR LIMIT-TO (PUBYEAR,2017) OR LIMIT-TO (PUBYEAR,2016) OR LIMIT-TO (PUBYEAR,2015) OR LIMIT-TO (PUBYEAR,2014) OR LIMIT-TO (PUBYEAR,2013) OR LIMIT-TO (PUBYEAR,2012) OR LIMIT-TO (PUBYEAR,2011)) AND (LIMIT-TO (SRCTYPE,"j"))
12-07-2021	Ovid Medline	Ovid MEDLINE(R) <1996 to August Week 3 2021> 1 exp Uterine Cervical Neoplasms/ 48683 2 Uterine Cervical Neoplasms.af. 48719 3 Cervical Cancer.af. 37377 4 exp Alphapapillomavirus/ 8338 5 Alphapapillomavirus.af. 2733 6 exp Papillomavirus Infections/ 31367 7 Papillomavirus Infection*.af. 28075

		8 Human papillomavirus*.af. 33426 9 HPV.af. 35627 10 papillomavirus*.af. 42280 11 Cervi* Cancer.af. 38169 12 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 86646 13 exp Self Administration/ 8841 14 Self Administration.af. 11764 15 self-sampl*.af. 682 16 self collect*.af. 1155 17 self administrat*.af. 12471 18 self screen*.af. 205 19 self-testing.af. 1129 20 self-test*.af. 1491 21 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 15594 22 exp "Africa South of the Sahara"/ 168852 23 sub-sahara* Africa.af. 19913 24 22 or 23 173452 25 12 and 21 and 24 101 26 limit 25 to yr="2011 -Current" 95 27 limit 26 to (female and humans) 95
14-07-2021	Cochrane	ID Search Hits #1 MeSH descriptor: [Alphapapillomavirus] explode all trees 247 #2 MeSH descriptor: [Uterine Cervical Neoplasms] explode all trees 2171 #3 ("Uterine Cervical Neoplasm*" OR "Cervical Cancer" OR Alphapapillomavirus OR "Human papillomavirus*" OR HPV OR papillomavirus*) (Word variations have been searched) 7022 #4 #1 OR #2 OR #3 6989 #5 MeSH descriptor: [Self Administration] explode all trees 778 #6 (self-sampl* OR "self collect*" OR "self Administ*" OR "self screen*") (Word variations have been searched) 6495 #7 #5 OR #6 1040 #8 MeSH descriptor: [Africa South of the Sahara] explode all trees 6811 #9 ("sub-Saharan Africa") (Word variations have been searched) 2037 #10 #8 OR #9 8279 #11 #4 AND #7 AND #10 8 Date range 2011-2021 Results 7
31-08-21	Grey Literature identified through other sources	“Human papillomavirus” OR “cervical cancer” AND “self-sampling” AND “sub-Saharan Africa”

Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
TITLE			
Title	1	**Human Papillomavirus Self-sampling for Cervical Cancer Screening among Women in sub-Saharan Africa: A Scoping Review Protocol**	1
ABSTRACT			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	4
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	4-5
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	N/A
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	7
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	7
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	7
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	8
Data charting process‡	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	9
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	6
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	10

Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	10

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
RESULTS			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	9
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	N/A
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	10
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	N/A
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	N/A
DISCUSSION			
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	11
Limitations	20	Discuss the limitations of the scoping review process.	11
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	12
FUNDING			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	13

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.

* Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.

† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).

‡ The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting.

§ The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).

From: Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMAScR): Checklist and Explanation. Ann Intern Med. 2018;169:467–473. doi: 10.7326/M18-0850.

BMJ Open

Human Papillomavirus Self-sampling for Cervical Cancer Screening among Women in sub-Saharan Africa: A Scoping Review Protocol

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Complete List of Authors:	Dzobo, Mathias; University of Pretoria Faculty of Health Sciences, School of Health Systems and Public Health Dzinamarira, Tafadzwa; University of Pretoria Faculty of Health Sciences, School of Health Systems and Public Health Kgarosi, Kabelo; University of Pretoria Faculty of Health Sciences, Department of Library Services Mashamba-Thompson, Tivani; University of Pretoria, Faculty of Health Sciences
Primary Subject Heading:	Research methods
Secondary Subject Heading:	Diagnostics, Health policy, Research methods, Sexual health, Global health
Keywords:	Gynaecological oncology < GYNAECOLOGY, Molecular diagnostics < INFECTIOUS DISEASES, Public health < INFECTIOUS DISEASES

Human Papillomavirus Self-sampling for Cervical Cancer Screening among Women in sub-Saharan Africa: A Scoping Review Protocol

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Abstract

Introduction

Evidence shows that women in sub-Saharan Africa have high rates of cervical cancer (CC) mortality compared to women in high-income countries. Effective screening programmes have significantly reduced the burden of CC in high-income countries. Self-sampling for Human papillomavirus testing (HPVSS) has been reported to increase the participation and engagement of women in CC screening. Before HPVSS can be introduced for CC screening there is a need to establish its acceptability among end-users to ensure the increase in CC screening rates. Here we outline a protocol for a scoping review aimed at mapping literature on the use and acceptability of HPVSS for screening CC in sub-Saharan Africa to reveal gaps to guide future research and practice.

Method

The scoping review protocol was developed according to Arksey and O'Malley and Levac *et al*, and guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews. We will search Scopus, PubMed, Medline Ovid, Cochrane, and Web of Science databases for evidence on the use and acceptability of HPVSS published between January 2011 and July 2021. We will also search grey literature in the form of dissertations/theses, conference proceedings, websites of international organizations such as the World Health Organisation, and relevant government reports reporting evidence on HPVSS programs for screening CC among women in sub-Saharan Africa.

Ethics and dissemination

No ethical approval is needed for the study as it will not include animals or human participants. The results of the proposed scoping review will be disseminated electronically in peer-reviewed journals, in print, and through conference presentations.

Keywords: Women; Human papillomavirus DNA tests; Self-sampling; cervical cancer, sub-Saharan Africa

Article Summary

Strengths and Limitations of this study:

- The results of this review will establish a baseline understanding of the use and acceptability of HPVSS for CC screening in SSA and expose gaps that exist
- Here we propose the use of an established scoping review methodology with a comprehensive search strategy that includes grey literature.
- The study will conduct a formal quality assessment of included studies guided by an established mixed methods appraisal tool.
- A limitation of the review is the potential to miss relevant articles given that review articles will not be considered for the study

Introduction

Despite being a largely preventable disease, cervical cancer (CC) incidence and mortality remain important indicators of global health inequality.[1] An estimated 90% of the globally recorded CC-related deaths are in low-and middle-income countries (LMICs), of which 8 out of 10 are recorded within the sub-Saharan African (SSA) region.[2] In addition, the high burden of HIV/AIDS further worsens the problem of CC in SSA.[3 4] CC screening has significantly reduced the burden of CC in high-income countries (HICs).[3 5] However, in low- and middle-income countries (LMICs), the burden of CC incidence and mortality is very high

due to the lack of organised CC screening services and low uptake of available screening services by women.[6-8] In 2018 the World Health Organisation (WHO) made a global call for the elimination of CC by end of the century.[9] Under the call, The WHO targets to screen 70% of women with a high-performance test by 35, and again by 45 years of age by 2030.[9] The WHO has recommended the use of a high-performance test like Human papillomavirus (HPV) DNA test for the screening of CC in women [10] and recent WHO guidelines now advocate for the use of self-sampling to screen CC among women.[11]

Self-sampling for HPV testing (HPVSS) is a process where a woman who wants to know whether she has a high-risk HPV infection uses a kit to collect a cervicovaginal sample from herself.[12-14] HPVSS has been shown to increase the participation of women in CC screening programmes by reducing individual and health system-related barriers to screening particularly in low-resource settings.[12 14] The lack of privacy, fear and shame of a pelvic exam, and long distances to health facilities have been cited as barriers to CC screening. [8 12] Important considerations for introducing HPVSS should consider the follow-up of women who screen positive for HPV as well as triage options with another method such as visual inspection with acetic acid to prevent overtreatment of HPV infections which in most cases are transient.[12 13] Before HPVSS can be incorporated into national screening programmes there is a need to determine its acceptability among the targeted end-users.

Findings from a systematic review by Tesfahunei et al revealed the effectiveness of HPVSS to increase CC screening uptake by women in SSA compared to standard clinician sampling[15]. However, the systematic review only considered randomised control trials and hence perceptions and experiences of women could not be explored. There is a need to map existing evidence on the acceptability of HPVSS by synthesising both quantitative and qualitative data as well as studies that employ a mixed-methods approach.

The purpose of this scoping review is to map the literature evidence on the use and acceptability of HPVSS for CC screening in SSA by synthesising data from quantitative and qualitative studies. It is anticipated that findings from this study will enable the researchers to identify research gaps and guide future research towards improved and increased participation of women in CC screening programmes. The results of this study will also guide policymakers in designing CC screening programmes based on HPVSS that are more acceptable to end-users to increase the uptake of CC screening services in SSA.

Methods and Analysis

This proposed scoping review is part of a multi-phase Ph.D. study investigating the use and acceptability of HPVSS for CC screening among women in SSA. The review will be developed according to the methodological framework proposed by Arksey and O'Malley[16] and Levac et al,[17] and guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR).[18] According to Arksey and O'Malley framework,[16 17] a scoping review follows five stages: (i) identify the research question, (ii) identify relevant studies, (iii) select eligible studies, (iv) charting the data, and (v) collating, summarising and reporting the results. Arksey and O'Malley also proposed an optional sixth stage, the consultation with key stakeholders to provide insights beyond those found in the literature. This scoping review will not include consultation with stakeholders.

Eligibility of the research question for a scoping review

The research question is: What is the evidence on the use and acceptability of HPVSS for CC screening of women in SSA?

The main objective is: To map out evidence on the use and acceptability of HPVSS for CC screening of women in SSA.

We used the following elements: (Population, Concept, and Context) to conceptualize the review question as depicted in Table 1.

Table 1: PCC for determining the eligibility of the research question.

Population	Asymptomatic females; 25 years and older residing in SSA
Concept	HPVSS programmes conducted between January 2011 and June 2021
Context	Countries in the SSA region

Identification of relevant studies

We will conduct a comprehensive search of relevant literature from the following electronic databases for articles published between January 2011 and June 2021: Scopus, PubMed, Medline Ovid, Cochrane, and Web of Science databases. We will search for randomized controlled trials, non-randomized controlled trials, and observational studies that reported evidence on HPVSS for CC screening. Review articles (narrative, scoping, systematic, meta-analysis, and meta-synthesis) were excluded. In addition, we will search for grey literature from university dissertations and theses from institutional repositories, government, and international organizations' reports such as the WHO. We will identify additional relevant studies by manually searching all references cited in the included studies to identify studies that have not been indexed by the electronic databases. The authors of the included articles will be contacted for missing data and review articles will not be included in this study.

The comprehensive search strategy will be co-developed by the principal investigator (PI), subject specialist, and university librarian to ensure the correct use of indexing terminology and Medical Subject Headings (MeSH) terms. The following keywords or MeSH terms will be used: 1) "cervical cancer" 2) "human papillomavirus" 3) "self-sampling" 4) "sub-Saharan Africa". Keywords may be refined to suit each database. Each search will be documented in detail showing the keywords/MeSH terms, date of search, electronic database, and the number of retrieved studies. We piloted the search strategy on all the electronic databases and the results of the search are presented in Supplementary File 1.

Selection of eligible studies

Relevant studies will be selected using the following criteria:

Inclusion criteria

- Articles reporting on evidence of HPVSS in women 25 years and older
- Articles reporting on the acceptability of HPVSS for CC screening

- Articles reporting on evidence of HPVSS in women residing in SSA
- Articles published between January 2011 and June 2021

Exclusion criteria

Articles will be excluded from the scoping review if they have the following characteristics:

- Articles that report on other methods of CC screening articles that do not report on acceptability, willingness, or preferences for HPVSS
- Articles reporting on evidence of HPVSS in women residing outside SSA
- Articles published before January 2011 and after June 2021
- Review articles

All eligible articles will be exported to an Endnote 20 library and duplicates will be removed. The articles will be screened in three stages, namely title, abstract and full article screening. The PI will screen titles and abstracts in parallel with the co-reviewer. After screening titles and abstracts, the reviewers will discuss any discrepancies in selected articles until a consensus is reached. Two independent reviewers will then screen the full texts of articles selected during the first stage. A third screener will resolve any discrepancies in selected articles after the full-text screening. Both abstract and full article screening will be guided by the above inclusion/exclusion criteria.

The level of agreement between screeners' results after screening abstracts and full articles will be determined by calculating Cohen's kappa statistic. The kappa statistic will be interpreted as follows: values < 0.1 indicate no agreement and 0.10-0.20 indicate none to slight, 0.21-0.40 as fair, 0.41-0.60 as moderate, 0.61-0.80 as substantial, and 0.81-1.00 as almost perfect agreement. We will report the screening results following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines[19] (Figure **1**).

Charting the data

We developed a data charting form to capture information from each relevant study. Two independent reviewers will pilot the data charting form before commencing with the scoping review. The data charting form will be modified based on the reviewers' feedback and it will constantly be updated throughout the scoping review. The form that will be used for data charting is presented in Table **2**.

Table 2. Data charting form.

Author & year of publication
Aim of study
Study population
Study setting (rural or urban)
Geography (SSA country where the study was conducted)
Number of women (sample size)
Age of women
Study design
Setting of self-sampling kits (health facility or home/community based)
Type of self-sampling device used
Main findings (acceptability of HPVSS)
Other significant findings

Collating, summarizing, and reporting the results

We will employ NVivo version 12 to extract themes from the included studies.We will conduct a content thematic analysis of the included studies. We will present a narrative account of the findings presenting the main concepts from the included articles in line with

our research question. Our study context is acceptability of self-sampling for HPV testing which is defined as the ease and comfort or willingness to perform cervicovaginal self-sampling[20]

Quality appraisal

We will use the mixed method appraisal tool (MMAT) version 2018 to evaluate the quality of the included studies.[21] Two independent reviewers will carry out the quality appraisal process. The following percentage scores will be used to grade the quality of evidence: i) ≤50% will represent low quality evidence ii) 51-75% will represent average quality evidence iii) 76-100% will represent high-quality evidence. This quality appraisal method will enable us to appraise a variety of study methods, i.e. qualitative, quantitative or mixed methods studies.[21]

Ethics and dissemination

No ethical approval is needed for the study because it will not include animals or human participants. The findings of this review will be disseminated electronically in peer-reviewed journals or print and presented at scientific conferences.

Patient and public involvement

In this protocol, there was no involvement of patients and the public.

Discussion

The elimination of CC is in line with the 2030 agenda for SDG 3 and targets that seek to ensure healthy lives and promote well-being for all at all ages.[22] The majority of women in LMICs including SSA lack access to CC screening services and where the services are available they are underutilised due to several barriers.[5] HPVSS has been demonstrated to increases the participation and engagement of under-screened and unscreened women in CC

screening programmes.[23]There have been several HPVSS interventions that have been conducted in SSA, however, a few studies have synthesised evidence on the acceptability of the intervention.[24] The proposed scoping review will map evidence on the use and acceptability of HPVSS in SSA. Getting prior information on studies conducted in SSA will help guide the implementation of HPVSS for CC screening in the region and other LMICs. The scoping review is part of a larger study that seeks to pilot an HPVSS programme for CC screening in Zimbabwe. The scoping review will synthesise existing literature evidence and reveal gaps in research and guide the methodology of the main study. This intervention has the potential to increase access to underserved women as well as increase their participation in CC screening.

In this scoping review, we will include evidence on the use and acceptability of HPVSS for screening women aged 25 years and older, the WHO recommends HPV testing for women aged 30 years and above because most HPV infections in young women are transient.[10] We have chosen to include studies published in the last decade (2011-2021) to capture recent evidence on HPVSS in SSA. In addition, the WHO recommended the use of HPV testing for CC screening in 2013,[10] therefore, we are likely to find studies where HPVSS interventions have been implemented in SSA in response to the WHO recommendation. Furthermore, studies reporting evidence on other methods of CC screening other than HPVSS will not be considered for this review as well as studies conducted outside SSA. A limitation of the review is the potential to miss relevant articles given that review articles will not be considered for the study and also the potential to miss important studies from other LMICs outside SSA.

We have chosen to map evidence on HPVSS in SSA because it has the highest burden of CC in the world and findings are more likely to apply to Zimbabwe which is a country in SSA.

We anticipate finding relevant studies reporting on the use and acceptability of HPVSS for screening CC in SSA. The findings of this review will help policymakers to design interventions that increase the uptake of CC screening services in SSA. Furthermore, the findings will guide further research on best practices of implementing an acceptable HPVSS programme in LMICs.

Abbreviations

CC: Cervical cancer

HPV: Human papillomavirus

HPVSS: Human papillomavirus self-sampling

LMICs: Low middle-income countries

MeSH*:* Medical Subject Headings

MMAT: Mixed method appraisal tool

PRISMA-ScR: Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for scoping review

SSA: sub-Saharan Africa

Declarations

Acknowledgements

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Author Contributions

MD conceptualized the study and prepared the draft proposal under the supervision of TPM-T. MD, TD, and TPM-T contributed to the development of the background and planned the output of the research as well as the design of the study. KK contributed to the development of the search strategy. MD prepared the manuscript, and TD and TPM-T critically reviewed it. All authors (MD, TD, KK, and TPM-T) contributed to the reviewed draft version of the manuscript and approved the final version.

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

None declared.

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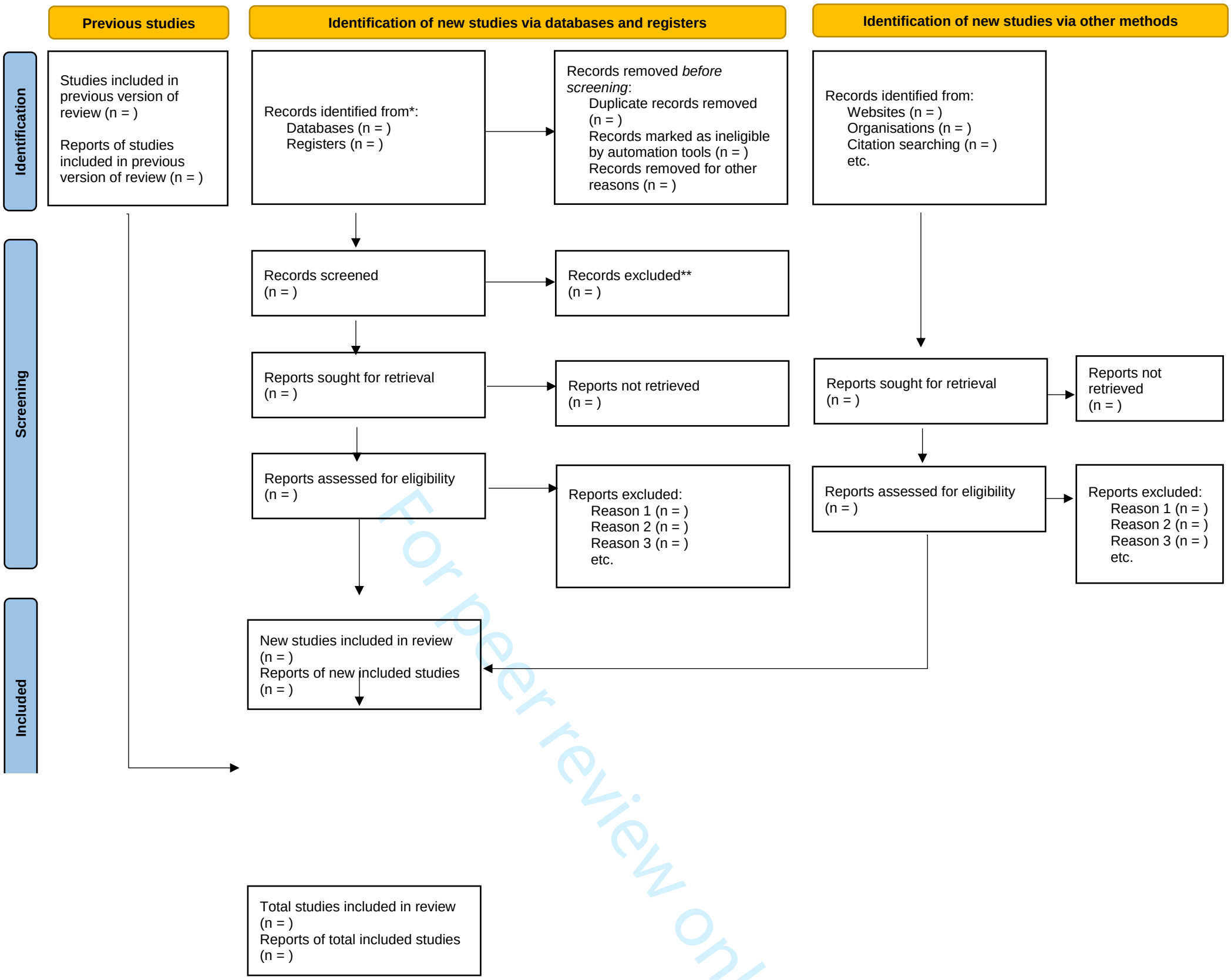
Figure. 1



PRISMA flow diagram of the study selection process

Supplementary File 1: Results of the search strategy for electronic databases and grey literature

Date of search	Electronic Database	Keywords/MeSH terms
14-06-2021	Web of Science	Human papillomavirus*" OR alphapapillomavirus OR hpv OR papillomavirus* OR "Cervical cancer*" OR "Uterine Cervical Neoplasm*" OR "cancer of the cervix" OR "uterine cervix tumor" AND "self-sampling" OR "self sampl*" OR "self collect*" OR "self screen*" OR screening AND Africa OR "sub-Saharan Africa" OR "Africa South of the Sahara" AND female OR woman OR women NOT algeria OR egypt OR libya OR morocco OR tunisia
06-07-2021	PubMed	((("Uterine Cervical Neoplasms"[Mesh] OR "Uterine Cervical Neoplasm*"[tw] OR "Cervical Cancer"[tw] AND (female[Filter])) OR ("Alphapapillomavirus"[Mesh] OR Alphapapillomavirus[tw] OR "Human papillomavirus*"[tw] OR HPV[tw] OR papillomavirus*[tw] AND (female[Filter]))) AND ("Self Administration"[Mesh] OR self-sampl*[tw] OR "self collect*"[tw] OR "self Administ*"[tw] OR "self screen*"[tw] AND (female[Filter]))) AND ("Africa South of the Sahara"[Mesh] OR "Africa Sub-Saharan"[tw] OR "Subsaharan Africa"[tw] OR "Sub-Sahara africa"[tw] AND (female[Filter])) Filters: in the last 10 years, Female
06-07-2021	Scopus	(TITLE-ABS-KEY(Africa* OR "sub-Saharan Africa" OR SS OR "Africa South of the Sahara" OR "Subsahara* Africa") AND TITLE-ABS-KEY("Human papillomavirus*" OR alphapapillomavirus OR hpv OR papillomavirus* OR "Cervical cancer*" OR "Uterine Cervical Neoplasm*" OR "cancer of the cervix" OR "uterine cervix tumor") AND TITLE-ABS-KEY("self-sampling" OR "self sampl*" OR "self collect*" OR "self screen*" OR screening) AND NOT TITLE-ABS-KEY(Algeria OR Egypt OR Libya OR Morocco OR Tunisia)) AND (LIMIT-TO (PUBYEAR,2021) OR LIMIT-TO (PUBYEAR,2020) OR LIMIT-TO (PUBYEAR,2019) OR LIMIT-TO (PUBYEAR,2018) OR LIMIT-TO (PUBYEAR,2017) OR LIMIT-TO (PUBYEAR,2016) OR LIMIT-TO (PUBYEAR,2015) OR LIMIT-TO (PUBYEAR,2014) OR LIMIT-TO (PUBYEAR,2013) OR LIMIT-TO (PUBYEAR,2012) OR LIMIT-TO (PUBYEAR,2011)) AND (LIMIT-TO (SRCTYPE,"j"))
12-07-2021	Ovid Medline	Ovid MEDLINE(R) <1996 to August Week 3 2021> 1 exp Uterine Cervical Neoplasms/ 48683 2 Uterine Cervical Neoplasms.af. 48719 3 Cervical Cancer.af. 37377 4 exp Alphapapillomavirus/ 8338 5 Alphapapillomavirus.af. 2733 6 exp Papillomavirus Infections/ 31367 7 Papillomavirus Infection*.af. 28075

		8 Human papillomavirus*.af. 33426 9 HPV.af. 35627 10 papillomavirus*.af. 42280 11 Cervi* Cancer.af. 38169 12 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 86646 13 exp Self Administration/ 8841 14 Self Administration.af. 11764 15 self-sampl*.af. 682 16 self collect*.af. 1155 17 self administrat*.af. 12471 18 self screen*.af. 205 19 self-testing.af. 1129 20 self-test*.af. 1491 21 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 15594 22 exp "Africa South of the Sahara"/ 168852 23 sub-sahara* Africa.af. 19913 24 22 or 23 173452 25 12 and 21 and 24 101 26 limit 25 to yr="2011 -Current" 95 27 limit 26 to (female and humans) 95
14-07-2021	Cochrane	ID Search Hits #1 MeSH descriptor: [Alphapapillomavirus] explode all trees 247 #2 MeSH descriptor: [Uterine Cervical Neoplasms] explode all trees 2171 #3 ("Uterine Cervical Neoplasm*" OR "Cervical Cancer" OR Alphapapillomavirus OR "Human papillomavirus*" OR HPV OR papillomavirus*) (Word variations have been searched) 7022 #4 #1 OR #2 OR #3 6989 #5 MeSH descriptor: [Self Administration] explode all trees 778 #6 (self-sampl* OR "self collect*" OR "self Administ*" OR "self screen*") (Word variations have been searched) 6495 #7 #5 OR #6 1040 #8 MeSH descriptor: [Africa South of the Sahara] explode all trees 6811 #9 ("sub-Saharan Africa") (Word variations have been searched) 2037 #10 #8 OR #9 8279 #11 #4 AND #7 AND #10 8 Date range 2011-2021 Results 7
31-08-21	Grey Literature identified through other sources	“Human papillomavirus” OR “cervical cancer” AND “self-sampling” AND “sub-Saharan Africa”

Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
TITLE			
Title	1	**Human Papillomavirus Self-sampling for Cervical Cancer Screening among Women in sub-Saharan Africa: A Scoping Review Protocol**	1
ABSTRACT			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	4
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	4-5
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	N/A
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	7
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	7
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	7
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	8
Data charting process‡	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	9
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	6
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	10

Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	10

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
RESULTS			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	9
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	N/A
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	10
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	N/A
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	N/A
DISCUSSION			
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	11
Limitations	20	Discuss the limitations of the scoping review process.	11
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	12
FUNDING			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	13

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.

* Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.

† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).

‡ The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting.

§ The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).

From: Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMAScR): Checklist and Explanation. Ann Intern Med. 2018;169:467–473. doi: 10.7326/M18-0850.